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ARCHIVES DIVISION
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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
06/25/2019 11:20 AM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 410
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILING CAPTION: Amending PDL May 23, 2019 DUR/P&T Action

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 08/17/2019 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Kim Stubenrauch
503-975-7026
kim.stubenrauch@dhsoha.state.or.us

500 Summer St. NE
Salem,OR 97301

Filed By:
Sandy Cafourek
Rules Coordinator

HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 08/15/2019
TIME: 10:30 AM - 11:30 AM
OFFICER: Kim Stubenrauch
ADDRESS: Human Services Building
500 Summer St. NE, Room 166
Salem, OR 97301
SPECIAL INSTRUCTIONS:
Written public comments end: August 17, 2019, at 5 p.m.
Send comments to HSD.rules@dhsoha.state.or.us

NEED FOR THE RULE(S):

The Pharmaceutical Services program administrative rules (division 121) govern Division payments for services provided to certain clients. The Division needs to amend OAR 410-121-0030 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the May 23, 2018, meeting. The Authority needs to implement changes to the Preferred Drug List to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

410-121-0030:
Preferred:
C1 esterase inhibitor
sumatriptan succinate syringe
zolmitriptan tablets

zolmitriptan rapid tablets
zolmitriptan nasal spray
meloxicam new formulation
dolutegravir/lamivudine tablets
evolocumab
exetimibe
exenatide microspheres
liraglutide
eltrombopag olamine
romiplostim
cholecalciferol (vitamin D3) Drops
aclidinium bromide
momentasone furoate
momentasone/formoterol
Non-Preferred:
gemfibrozil
delavirdine mesylate
filgrastim-sndz
elvitegravir tablet
Stavudine™
Clerical - Various clerical changes were made to system class, drug and form names.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

ORS 414.353, 414.354, and Or Law 2011, chapter 720 (HB 2100): https://www.oregonlaws.org/ors/414.361

FISCAL AND ECONOMIC IMPACT:

None

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) This permanent filing is needed in order for the legislatively mandated Pharmacy & Therapeutics Committee to convene and conduct official business under the auspices of the Oregon Health Authority. It is also necessary for the health and safety of Oregon Health Plan recipients receiving drugs and prior authorizations. (2) (a) Small businesses will not be affected by this rule. (b) There is no anticipated increase. (c) There is no anticipated increase.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the development of this rule as it will not affect them.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

AMEND: 410-121-0030

RULE SUMMARY: The Pharmaceutical Services Program administrative rules (Division 121) govern Division payments

for services provided to certain clients. The Division needs to amend rules as follows:
410-121-0030:
Preferred:
C1 esterase inhibitor
sumatriptan succinate syringe
zolmitriptan tablets
zolmitriptan rapid tablets
zolmitriptan nasal spray
meloxicam new formulation
dolutegravir/lamivudine tablets
evolocumab
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Non-Preferred:
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delavirdine mesylate
filgrastim-sndz
elvitegravir tablet
Stavudine™
Clerical - Various clerical changes were made to system class, drug and form names.

CHANGES TO RULE:

410-121-0030
Practitioner-Managed Prescription Drug Plan ¶

(1) The Practitioner-Managed Prescription Drug Plan (PMPDP) is a plan that ensures that OHP fee-for-service clients have access to the most effective prescription drugs appropriate for their clinical conditions at the best possible price: ¶
(a) Licensed health care practitioners, who are informed by the latest peer reviewed research, make decisions concerning the clinical effectiveness of the prescription drugs; ¶
(b) Licensed health care practitioners also consider the client's health condition, personal characteristics, and the client's gender, race, or ethnicity. ¶
(2) PMPDP Preferred Drug List (PDL): ¶
(a) The PDL is the primary tool the Division uses to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs; ¶
(b) The PDL contains a list of prescription drugs that the Division, in consultation with the Drug Use Review (DUR)/Pharmacy & Therapeutics Committee (P&T), has determined represent the most effective drugs available at the best possible price; ¶
(c) The PDL shall include drugs that are Medicaid reimbursable and the Food and Drug Administration (FDA) has determined to be safe and effective. ¶

(3) PMPDP PDL Selection Process: ¶
(a) The Division shall utilize the recommendations made by the P&T that result from an evidence-based evaluation process as the basis for selecting the most effective drugs; ¶
(b) The Division shall ensure the drugs selected in section (3)(a) are the most effective drugs available for the best possible price and shall consider any input from the P&T about other FDA-approved drugs in the same class that are available for a lesser relative price. The Division shall determine relative price using the methodology described in section (4); ¶
(c) The Division shall evaluate selected drugs for the drug classes periodically: ¶
(A) The Division may evaluate more frequently if new safety information or the release of new drugs in a class or other information makes an evaluation advisable; ¶
(B) New drugs in classes already evaluated for the PDL shall be non-preferred until the new drug has been reviewed by the P&T; ¶
(C) The Division shall make all revisions to the PDL using the rulemaking process and shall publish the changes on the Division's Pharmaceutical Services provider rules website. ¶
(4) Relative cost and best possible price determination: ¶
(a) The Division shall determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective; ¶
(b) The Division may also consider dosing issues, patterns of use, and compliance issues. The Division shall weigh these factors with any advice provided by the P&T in reaching a final decision. ¶
(5) Pharmacy providers shall dispense prescriptions in the generic form unless:¶
(a) The practitioner requests otherwise pursuant to OAR 410-121-0155;¶
(b) The Division notifies the pharmacy that the cost of the brand name particular drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.¶
(6) The exception process for obtaining non-preferred physical health drugs that are not on the PDL drugs shall be as follows: ¶
(a) If the prescribing practitioner in their professional judgment wishes to prescribe a physical health drug not on the PDL, they may request an exception subject to the requirements of OAR 410-121-0040; ¶
(b) The prescribing practitioner must request an exception for physical health drugs not listed in the PDL subject to the requirements of OAR 410-121-0060; ¶
(c) Exceptions shall be granted when: ¶
(A) The prescriber in their professional judgment determines the non-preferred drug is medically appropriate after consulting with the Division or the Oregon Pharmacy Call Center; or ¶
(B) Where the prescriber requests an exception subject to the requirement of section (6)(b) and fails to receive a report of PA status within 24 hours, subject to OAR 410-121-0060. ¶
(7) Table 121-0030-1, PMPDP PDL dated ~~October~~July ~~15~~, 201~~8~~,9 is adopted and incorporated by reference and is found at: www.orpdl.org.
Statutory/Other Authority: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, ORS 413.032, ORS 414.312, ORS 414.316
Statutes/Other Implemented: ORS 414.065, 414.325, 414.334, 414.361, 414.369, 414.371, 414.353, 414.354